UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LINDA S. MANSFIELD, MARY G. ROSSANO, ALICE J. MURPHY and RUTH A. VRABLE

Appeal No. 2005-2386
Application No. 09/670,096

ON BRIEF

Before GRIMES, GREEN, and LEBOVITZ Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2 and 21,[1] all of the pending claims, which are reproduced below:

[1] An amendment after final was filed concurrently with the Appeal Brief, dated August 20, 2004, and stamped August 23, 2004. Appellants state in the Appeal Brief that an Amendment was filed August 20, 2004, and in response, the examiner in the Examiner's Answer merely states that appellants' statement is correct, but does not explicitely state that the amendment was entered. But because the rejection of claim 2 under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis was withdrawn, and the amendment after final remedied that issue, we infer that the amendment was entered. Thus, the claims as reproduced here are as amended by the August 23, 2004, amendment after final.

1. A composition for treating an equid infected with Sarcocystis neurona comprising a mixture of isolated antibodies against a 16 ±4 kDa antigen of Sarcocystis neurona and isolated antibodies against a 30 ±4 kDa antigen of Sarcocystis neurona wherein the antibodies are from serum of an animal immunized with the antigen and wherein the mixture is in a pharmaceutically acceptable carrier.

2. The method of claim 21 wherein the antibodies are monoclonal antibodies.

21. A method for treating an equid infected with Sarcocystis neurona comprising:

(a) providing a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen, both of which are specific to Sarcocystis neurona, wherein the antibodies are selected from the group consisting of polyclonal antibodies from serum from an animal immunized with the antigen and monoclonal antibodies from a hybridoma, and wherein the antibodies are in a pharmaceutically acceptable carrier; and

(b) inoculating the equid with the antibodies in the carrier to treat the equid.

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way so as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention. After careful review of the record and consideration of the issue before us, we reverse.

DISCUSSION

Claims 1, 2 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first

paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

In making the enablement rejection, the examiner engages in the analysis of the factors as set forth in In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Examiner's Answer, page 5.

The examiner notes that given the high rate of exposure of horses to S. neurona and the low incidence of clinical equine protozoal myeloencephalitis (EPM), "indicate[s] that most horses develop effective immunity (no clinical symptoms of disease) that may prevent merozoite entry into the central nervous system." Id. at 6. The examiner goes on to state that the pathogenesis of the disease is not fully understood, and that clinical manifestations of the disease only occur in a small percentage of seropositive horses, citing Cutler[2] in noting

[2] Cutler et al. (Cutler), "Immunoconversion against Sarcocystis neurona in normal and dexamethasone-treated horses challenged with S. neurona sporocysts," Veterinary Parasitology, Vol. 95, pp. 197-210 (2001).

that "it is important and necessary to identify factors that govern progression from an apparent infection to clinically evident neurological disease, EPM . . . in horses." Id.

According to the examiner, "[t]he treatment of S. neurona infection in an equid with antibodies is highly complex and unpredictable because relative to the infection, the development of clinical spreading of the disease i.e., merozoite entry into the central nervous system crossing blood brain barrier is not known as most of the horses develop immunity without EPM." Examiner's Answer, page 6. As "the prior art does not teach administration of a mixture of isolated antibodies against a 16 kD antigen of S. neurona and isolated antibodies against a 30 kD antigen of S. neurona to an infected horse with EPM which would resolve the infection in CNS[,] . . . [t]hus there is a lack of understanding in the art with respect to the pathogenesis of S. neurona infection in horses that develop EPM." Id. at 7.

The examiner also relies on Liang 1998[3] to support the proposition that "not all antibodies generated during infection will neutralize the merozites." Examiner's Answer, page 7. The examiner asserts that from Liang 1998 it appears that extended exposure to antiserum appears to be necessary, and that in vitro data do not necessarily correlate to the results that will be obtained in vivo. See id. Moreover, according to the examiner, "it is unclear whether such

[3] Liang et al. (Liang 1998), "Evidence that Surface Proteins Sn14 and Sn16 of *Sarcocystis neurona* Merozoites Are Involved in Infection and Immunity," Infection and Immunity, Vol. 66, No. 5, pp. 1834-1838 (1998).

an immunotherapy can be used to treat all horses that are infected with S. neurona." Id. at 8. The examiner is also concerned that the specific antibodies used in the claimed immunotherapeutic methods are not characterized. See id.

We do not find that the examiner has provided evidence and/or reasoning that the claims are not enabled by the specification. As noted by appellants, "since many horses exposed to Sarcocystis neurona do not have clinical signs of EPM but have immunity to Sarcocystis neurona the serum antibodies are likely effective for protecting against the parasite." Appeal Brief, page 9. Given that, as further noted by appellants, "it would appear to be reasonable to believe that horses with EPM have an inadequate immune response to the parasite which is not sufficient to prevent entry of the parasite into the CNS and that boosting the immune response with antibodies against the 16 and 30 kDa antigens might provide a sufficient boost to an infected horse's immune response to inhibit entry of the parasite into the CSF." Id. at 16.

Moreover, Liang 1998 teaches that Sarcocystis neurona is sensitive to specific antibodies, and thus does not support the examiner's contention that the claims are not enabled. In regard to the examiner's statement that "it is unclear whether such an immunotherapy can be used to treat all horses that are infected with S. neurona," there is no requirement that the claimed method work with all horses that are infected with S. neurona.

In addition, Appellants submitted a declaration on April 1, 2003, Appendix B to the Appeal Brief, demonstrating that both the 16 and 30 kDa antigens

appeared to be more neutralizing than either antibody alone. See Appeal Brief, page 14. In response, the examiner argues that although "[t]he Declaration provides evidence that CSF from infected horses contains antibodies to 16kD and 30kD [antigens] and such antibodies neutralize the merozoites in vitro (neutralization assays) only," the declaration "does not provide any evidence that the claimed composition comprising said antibodies are useful for treating an equid infected with S. neurona." Examiner's Answer, page 13.

Thus, the examiner's principal concern appears to be that the specification provides no in vivo examples of treating a horse. See, e.g., Examiner's Answer, pages 6 and 8. The examiner notes that the specification "only discloses that multiple isolates of merozoites have been obtained by culturing sporozoites from opossum," id. at 8, and that "[t]he specification . . . provides no working examples demonstrating . . . enablement for the claimed composition or a method that is required in this under developed art. The specification only teaches culturing sporocysts and merozoites," id. at 9.

The presence or absence of a working example, however, is not determinative on the issue of enablement. It is just one factor that is to be weighed with the other factors. In the case at issue, the examiner has not met the burden of demonstrating that the specification does not enable the claims, and the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement, is reversed.

OTHER ISSUES

Appellants' and the examiner's attention is directed to related Appeal Number 2004-1976, U.S.S.N. 09/669,843. That appeal contained a claim to:

> A monoclonal mixture comprising an antibody that selectively binds to a 16 ± 4 kDa antigen of Sarcocystis neurona and a monoclonal antibody that selectively binds to a 30 ± 4 kDa antigen of Sarcocystis neurona wherein the antigens are separately isolated from Sarcocystis neurona merozoites by two-dimensional polyacrylamide gel electrophoresis and separately used to produce hybridomas which produce the monoclonal antibodies for the mixture.

In the 2004-1976 appeal, we affirmed a rejection under 35 U.S.C. § 103(a) over the combination of Liang 1998 or Liang 1997[4] and Harlow.[5]

Similarly, in the instant appeal, claim 1 is directed to:

A composition for treating an equid infected with Sarcocystis neurona comprising a mixture of isolated antibodies against a 16 ±4 kDa antigen of Sarcocystis neurona and isolated antibodies against a 30 ±4 kDa antigen of Sarcocystis neurona wherein the antibodies are from serum of an animal immunized with the antigen and wherein the mixture is in a pharmaceutically acceptable carrier.

The recitation of "for treating an equid infected with Sarcocystis neurona" is a statement of intended use, and not a patentable limitation. See In re

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[4] Liang et al. (Liang 1997), "Micropreparative High Resolution Purification of Proteins by a Combination of Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis, Isoelectric Focusing, and Membrane Blotting," Anal. Biochem., Vol. 250, pp. 61-65 (1997).

[5] Harlow et al. (Harlow, Antibodies, A laboratory Manual, Chapter 6, Col Spring Harbor Press (1988).

Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Upon return of the appeal, the examiner may wish to consider the patentability of instant claim 1 in view of the references and the rejection as set forth in Appeal Number 2004-1976.

CONCLUSION

Because the examiner has not set forth a prima facie case of unpatentability, the rejection of claims 1, 2 and 21 under 35 U.S.C. § 112, first paragraph, for lack of enablement, is reversed. Upon receipt of the case, however, the examiner may wish to consider the patentability of claim 1 in view of the rejection under 35 U.S.C. § 103(a) as set forth in related Appeal 2004-1976.

REVERSED

Eric Grimes)
Administrative Patent Judge)
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